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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,463	08/19/1999	JAN BRUNDELL	100096.401	2926

7590

05/07/2002

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EXAMINER

TURNER, SHARON L

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/07/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,463

Applicant(s)

Brundell et al.

Examiner

Sharon L. Turner, Ph.D.

Art Unit

1647



-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 2-12-02

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 19-24 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 19-24 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

20) ☐ Other:

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DETAILED ACTION

Oath/Declaration

1. Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on application PCT/SE97/01164 filed 6-27-1996. However, Applicant's have not fully complied with the requirements of 37 CFR 1.63(c), since the oath or declaration acknowledges the filing of the foreign application but incorrectly notes the filing date as 6-05-1996. It is noted that instant case is a 371 application. Applicants may have wished to claim foreign priority of another application filed 05 June 1996 although no such application is identified. A new oath or declaration is required in the body of which the present application should be identified by the correct filing date. The effective filing date is 6-27-1996 as indicated in the 903. Prior art is cited accordingly.

Election/Restriction

2. Applicant's election of Group VI, SEQ ID NO:2 in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Eldik et al., PNAS 81:6034-38, October 1984, Okada et al., US 5320,944 June 14, 1994 and Shibue et al., 5,240,863 August 31, 1993.

Van Eldik et al., teach monoclonal antibodies to S100 beta having the amino acid sequence of SEQ ID NO:2 and SEQ ID NO:3. The antibodies specifically react with S100 beta as determined via ELISA (enzyme linked immunosorbant assay) assay, see in particular Abstract, Production of Monoclonal Antibodies and ELISA, p. 6034-6035.

Van Eldik et al., do not teach dual antibody (sandwich) ELISA with magnetic carrier particle and detection via luminol luminescence.

Okada et al., teach dual antibody ELISAs wherein the antibodies are bound to a carrier comprised of a magnetic particle, see in particular Immunoassay method, column 5-6 and Example 1-9. Okada notes that the detection may be via luminol-H₂O₂ (for peroxidase), see in particular column 5, lines 47-48.

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Shibue et al., teach dual antibody ELISAs wherein the immunoreactant measuring is via electrochemiluminescence in particular with the substance luminol, see in particular column 1, line 17 and Utility, columns 5-6. Shibue also notes that the invention is carried out with suitable carrier particles such as magnetic metal carrier particles, see in particular column 2, lines 40-41

Thus it would have been prima facie obvious to the skilled artisan to modify the ELISA of Van Eldik with S100 beta monoclonal antibodies with the dual antibody sandwich assay of Okada et al and Shibue using magnetic carrier immobilization and detection via chemiluminescence. One of skill in the art would have been motivated to perform such a soluble sandwich assay using an antibody attached to a magnetic particle carrier and an antibody labeled with luminol based on the teachings of the advantages of magnetic carrier beads and luminol in isolation and detection of the immunoreactive aggregate and the advantages in sensitivity and detection using such modifications as taught by Okada and Shibue. One of skill in the art would have expected positive results using such modification based on the positive success achieved in the Van Eldik, Okada and Shibue references and the high skill in the art of ELISAs. Thus, the cumulative reference teachings render the invention obvious to one skilled in the art.

Status of Claims

5. No claims are allowed.

6. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice

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published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
May 1, 2002


GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600